

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

*Montgomery County Board of County
Commissioners et al. v. Cardinal Health,
Inc., et al.*
Case No. 18-op-46326-DAP

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**Meijer Defendants' Answer to Plaintiff's
Supplemental and Amended Allegations to be Added to "Short Form
for Supplementing Complaint and Amending Defendants and Jury Demand"**

Defendants Meijer, Inc., Meijer Distribution, Inc., and Meijer Stores Limited Partnership (collectively “Meijer”), through their undersigned counsel and pursuant to the Stipulated Order Regarding Answering the May 19, 2021 Amended Complaints in the Five New Pharmacy Bellwether Cases (MDL ECF No. 3853, the “Stipulated Order”), answer Plaintiff’s “Supplemental and Amended Allegations to be Added to ‘Short Form for Supplementing Complaint and Amending Defendants and Jury Demand’” (ECF No. 27, the “Amended Complaint”) as follows:

Statements Pursuant to Stipulated Order

Pursuant to the Stipulated Order (¶ 4), Meijer has no obligation to answer any prior complaints or pleadings incorporated by reference into the Amended Complaint. By not answering such prior complaints or pleadings, Meijer does not admit any of the allegations in those prior complaints or pleadings and reserves all defenses to the claims and allegations of the prior complaints or pleadings. Meijer’s failure to answer any prior complaint or pleading in responding to the allegations of the Amended Complaint shall not be construed as an admission of any allegation in those prior complaints or pleadings and shall not be a basis for a default judgment with respect to any claims asserted in those prior complaints or pleadings. On this basis, Meijer

does not answer paragraphs 3, 765-766, or 770 of the Amended Complaint. Meijer denies any incorporated allegations generally to the extent they are directed at Meijer and denies them specifically to the extent they claim Meijer acted improperly or failed to comply with the law. To the contrary, Meijer at all times acted properly and in accordance with its legal obligations. Meijer denies any and all liability to Plaintiff in this action.

Meijer answers only for itself. Pursuant to the Stipulated Order (¶ 5), Meijer has no obligation to answer any allegation or paragraph directed solely to other defendants and may so state in its Answer. On this basis, Meijer does not answer paragraphs 37-83, 190-474, 501-505, 507-524, 528-529, 532-533, 537-538, 545-546, 555-559, 565-594, 601-612, 618-665, or 843-844 of the Amended Complaint.

Pursuant to the Stipulated Order (¶¶ 6, 9), Meijer may identify the paragraphs that it denies in their entirety by paragraph number. Additionally, the Amended Complaint contains purported references to several documents and third-party publications and statements that have often been excerpted, paraphrased, characterized, and otherwise taken out of context. These third-party publications and statements should be considered, if at all, in context and in unmodified form, and Meijer hereby respectfully refers the Court to the respective third-party publications and statements for their complete contents. On this basis, Meijer denies paragraphs 1-2, 4-33, 35-36, 87-102, 104-189, 475-495, 497-500, 505-506, 525-527, 530-531, 534-536, 539-544, 547-554, 560-564, 595-600, 613-617, 666-764, 767-769, 771-779,¹ 800-842, and 845 of the Amended Complaint: as factually incorrect; as calling for legal conclusions; as purporting to state facts as to which Meijer lacks sufficient knowledge to respond; based on the County's vague, ambiguous,

¹ Meijer notes that the Amended Complaint skips from paragraph 779 to paragraph 800. Meijer therefore does not respond to paragraphs 780-799 because they do not exist.

overly generalized and/or improper allegations and characterizations; and/or to the extent they purport to quote from sources other than the Amended Complaint, including undisclosed or unidentified sources.

Meijer specifically denies any and all allegations that it distributed or dispensed opioid medications in violation of the Controlled Substances Act or associated regulations, any Ohio laws or regulations, or any other state or federal laws or regulations. Meijer also specifically denies that its distribution of prescription opioid medications to Meijer pharmacies, or dispensing of those medications from those Meijer pharmacies, caused or contributed to any public nuisance.

Answer to Remaining Allegations

Pursuant to the Stipulated Order (¶ 8), Meijer responds to specific paragraphs of the Amended Complaint as follows:

34. This Court has personal jurisdiction over all Defendants under R.C. 2307.382 because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or deriving substantial revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

ANSWER: Meijer does not contest personal jurisdiction. Except as so stated, denied.

84. Defendant Meijer, Inc. has its principle [sic] place of business in Grand Rapids, Michigan and upon information and belief, is a Michigan corporation. Defendants Meijer Distribution, Inc. and Meijer Stores Limited Partnership are each based in Grand Rapids, Michigan and upon information and belief, each is a Michigan corporation.

ANSWER: Meijer admits: Meijer, Inc. and Meijer Distribution, Inc. are Michigan corporations; and all three Meijer defendants are based in Grand Rapids, Michigan. Except as so stated, denied.

85. Meijer, Inc., through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy. Orders of controlled substances came from Meijer Distribution, Inc. and other wholesalers. Meijer Stores Limited

Partnership, upon information and belief, operates each pharmacy in the County as a “d/b/a” entity.

ANSWER: Meijer admits: Meijer Distribution, Inc. and other firms distribute prescription medications, including controlled substances, to Meijer pharmacies; and Meijer Stores Limited Partnership operates each Meijer pharmacy in Montgomery County, Ohio. Except as so stated, denied.

86. Defendants Meijer, Inc., Meijer Distribution, Inc., and Meijer Stores Limited Partnership are collectively referred to as “Meijer.” Meijer operates over 200 stores across Michigan, Ohio, Indiana, Illinois, and Kentucky. Upon information and belief, at all times relevant to this Complaint, Meijer distributed and/or sold prescription opioids throughout these states, including in Ohio and the County specifically.

ANSWER: Meijer admits: Plaintiff refers to these entities as Meijer; there are more than 200 Meijer stores in the listed states; Meijer Distribution, Inc. distributed prescription medications, including prescription opioid medications, to Meijer pharmacies; and Meijer pharmacies filled valid prescriptions, including prescriptions for opioid medications, in Montgomery County and elsewhere in Ohio. Except as so stated, denied.

103. Each of the Chain Pharmacies does substantial business across the United States, while Meijer’s business is focused in Ohio and nearby states. This business includes the distribution and sale of prescription opioids.

ANSWER: Meijer admits that it does business in Ohio, including by distributing medications to, and dispensing medications from, pharmacies that Meijer operates. Except as so stated, denied.

496. Upon information and belief, Meijer integrated OARRS access into its 41 Ohio pharmacies in 2017.

ANSWER: Meijer admits it integrated OARRS into its Ohio dispensing systems in or around 2017. Except as so stated, denied.

Pursuant to the Stipulated Order (¶ 10), all allegations in the Amended Complaint that Meijer does not specifically admit, in whole or in part, are denied. Meijer expressly denies each

and every allegation contained in the Amended Complaint, including without limitation any allegations contained in the numbered and unnumbered paragraphs, subparagraphs, headings, subheadings, footnotes, and exhibits of the Amended Complaint, unless otherwise stated herein. Meijer specifically denies any liability to Plaintiff. To the extent that the titles, headings, subheadings, paragraphs, and footnotes of the Amended Complaint are intended to be allegations directed to Meijer, they are denied.

Meijer reserves the right to seek to amend and supplement its Answer as may be appropriate or necessary.

Affirmative Defenses

Pursuant to the parties' stipulation and the Court's order (MDL ECF No. 3853, ¶ 11), Meijer is required to state only its affirmative defenses to the County's purported public nuisance claims against Meijer. Meijer asserts the following affirmative defenses:

First Affirmative Defense

The Amended Complaint fails to state a claim against Meijer upon which relief can be granted.

Second Affirmative Defense

The Court lacks subject matter jurisdiction over the claims asserted by the Plaintiff.

Third Affirmative Defense

The Court lacks subject-matter jurisdiction to address any violations of the Ohio Pharmacy Practice Act, either (1) for failure to comply with any administrative remedies under the Act, (2) because the Ohio Pharmacy Practice Act does not give rise to a private cause of action, and/or (3) because the Court has already dismissed any claims or causes of action arising from or related to the Ohio Pharmacy Practice Act.

Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines and because its claims implicate issues of statewide importance that are reserved for state regulation.

Fifth Affirmative Defense

Plaintiff lacks standing to assert its claims in this action, including claims indirectly maintained on behalf of its citizens and claims brought as *parens patriae*.

Sixth Affirmative Defense

Meijer followed good faith dispensing practices and its pharmacists properly fulfilled their corresponding responsibility to review prescriptions for indications that they were not issued in the usual course of professional treatment. 21 CFR §1306.04(a). Meijer pharmacists did not knowingly fill any prescriptions that they knew were not valid and legitimate.

Seventh Affirmative Defense

Plaintiff's claims are barred by the doctrine of unclean hands.

Eighth Affirmative Defense

Plaintiff's claims are barred by the doctrine of *in pari delicto*.

Ninth Affirmative Defense

Plaintiff's claims are not ripe and/or have been mooted.

Tenth Affirmative Defense

Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality.

Eleventh Affirmative Defense

Plaintiff's claims are barred because Plaintiff is not the real party in interest.

Twelfth Affirmative Defense

Plaintiff's claims are subject to all defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf Plaintiff seeks to recover.

Thirteenth Affirmative Defense

Any injuries and/or damages sustained by Plaintiff were caused or contributed to by the negligent or intentional conduct of Plaintiff and/or other persons, firms, corporations, or entities over whom Meijer had no control or right of control and for whom it is not responsible.

Fourteenth Affirmative Defense

A specific percentage of the tortious conduct that proximately caused the injury or loss to person or property is attributable to (i) Plaintiff, (ii) other parties from whom Plaintiff seeks recovery, and (iii) persons from whom Plaintiff does not seek recovery in this action, including, but not limited to, prescribing practitioners, non-party pharmacies and pharmacists, individuals and entities involved in diversion and distribution of prescription opioids, individuals and entities involved in the import, distribution, and sale of illegal opioids, individuals involved in procuring diverted prescription opioids and/or illegal drugs, delivery services, federal, state, and local government entities, and health insurers and pharmacy benefit managers, pursuant to the doctrine of comparative fault.

Fifteenth Affirmative Defense

Any verdict or judgment that might be recovered by Plaintiff must be reduced pursuant to Ohio Rev. Code §§ 2315.32-35, 2307.22 and 2307.23 to account for the acts or omissions attributable to Plaintiff and to account for the acts or omissions attributable to one or more persons from whom Plaintiff does not seek recovery in this action.

Sixteenth Affirmative Defense

Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or, with reasonable certainty, will indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss from any collateral source or any other applicable law.

Seventeenth Affirmative Defense

Any verdict or judgment that might be recovered by Plaintiff must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject drugs, or damages recovered or recoverable by other actual or potential plaintiffs. Any damages that Plaintiff may recover against Meijer must be reduced to the extent they unjustly enrich Plaintiff.

Eighteenth Affirmative Defense

Plaintiff has failed to comply with the requirement that it identify each patient in whose claim(s) it has a subrogation interest and on whose behalf it has incurred costs.

Nineteenth Affirmative Defense

Plaintiff fails to plead that it reimbursed any prescriptions for any opioid dispensed by Meijer that allegedly should not have been dispensed; that Meijer's allegedly improper conduct caused the issuance of any unauthorized, medically unnecessary, or harmful opioid prescriptions; or that any specific prescription was unauthorized, medically unnecessary, or harmful.

Twentieth Affirmative Defense

Plaintiff's claims against Meijer do not arise from the same transactions or occurrences as its claims against other defendants, as required for joinder of parties.

Twenty-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of superseding and intervening acts and/or causation.

Twenty-Second Affirmative Defense

Meijer denies all types of causation, including without limitation cause-in-fact, proximate cause and producing cause, with respect to the claims asserted against Meijer.

Twenty-Third Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Meijer has no legal duty to protect Plaintiff from the intentional criminal acts of third persons. Such criminal acts are superseding causes that extinguish any liability.

Twenty-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were due to illicit use or abuse of medications.

Twenty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bar Plaintiff from recovering payments it allegedly made on behalf of its residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

Twenty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Dormant Commerce Clause of the United States Constitution.

Twenty-Seventh Affirmative Defense

The Amended Complaint fails to state a claim against Meijer because Plaintiff cannot establish a right common to the general public with which Meijer unreasonably interfered.

Twenty-Eighth Affirmative Defense

Meijer did not owe or breach any statutory or common law duty to Plaintiff.

Twenty-Ninth Affirmative Defense

Meijer performed and discharged any and all obligations and legal duties arising out of the matters alleged in the Amended Complaint.

Thirtieth Affirmative Defense

Plaintiff's claims against Meijer are barred, in whole or in part, because Meijer complied at all relevant times with all applicable laws, including all legal and regulatory duties.

Thirty-First Affirmative Defense

Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on Meijer.

Thirty-Second Affirmative Defense

To the extent applicable, Meijer is not a “wholesale distributor” as alleged in the Amended Complaint—but rather distributes medications only to its own pharmacies—and, as a result, the Amended Complaint is premised on a mistaken allegation against Meijer and should be dismissed against Meijer for that reason.

Thirty-Third Affirmative Defense

Plaintiff's claims are barred by the Learned Intermediary Defense, based on the allegations against Meijer, because Meijer fills valid prescriptions written by a physician acting in the capacity of a learned intermediary.

Thirty-Fourth Affirmative Defense

Any and all of the injuries or damages suffered by Plaintiff resulted solely from conduct and/or conditions for which Meijer is not responsible and for which it cannot be held liable.

Thirty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the harm alleged was proximately caused by the negligence, gross negligence, or intentional and malicious acts of intervening third parties not under Meijer's control.

Thirty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by the misuse of the medications involved, by failure to use the medications properly, and/or by the alteration, modification, or criminal misuse of medications prescribed by third parties over whom Meijer had no control.

Thirty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because neither the users of the subject prescription medications nor their prescribers relied to their detriment upon any statement by Meijer in determining to use or prescribe the subject prescription medications.

Thirty-Eighth Affirmative Defense

Plaintiff's claims against Meijer are improperly joined with Plaintiff's claims against other Defendants and must be severed.

Thirty-Ninth Affirmative Defense

Meijer and its pharmacists reasonably relied upon the prescribers who issued the prescriptions and have the primary "responsibility for the proper prescribing and dispensing of controlled substances". 21 CFR 1306.04(a).

Fortieth Affirmative Defense

Plaintiff's claims against Meijer are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and/or ratification.

Forty-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by Plaintiff's comparative or contributory fault including without limitation, on information and belief, its failure to:

- a. Develop and implement adequate policies and procedures to license and/or monitor physicians and other professionals prescribing the controlled substances at issue in the Amended Complaint, and to discipline and/or terminate the licenses of those issuing prescriptions for other than legitimate purposes;
- b. Develop and implement adequate policies and procedures to license, monitor and/or inspect pain management clinics prescribing the controlled substances at issue in the Amended Complaint, and to discipline and/or terminate the licenses of those issuing prescriptions for other than legitimate purposes;
- c. Develop and implement adequate policies and procedures to license, monitor and/or inspect pharmacies, pharmacists and other dispensers to ensure that they filled only legitimate prescriptions for controlled substances at issue in the Amended Complaint, and to discipline and/or terminate the licenses of those dispensing such prescription drugs for other than legitimate purposes;
- d. Develop and mandate use of an effective controlled substance monitoring database to identify rogue pharmacies, other dispensers and doctors, and drug abusers and take appropriate action against them;
- e. Develop, implement and adequately fund prescription drug abuse prevention and treatment programs;
- f. Develop, implement and adequately fund programs to address homelessness;
- g. Develop, implement and adequately fund mental and behavioral health programs and services; and/or

h. Adequately police the illicit diversion and consumption of prescription medications, and/or enforce the Ohio Controlled Substances Act, the Ohio Pharmacy Policy Act and regulations promulgated thereunder.

Forty-Second Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff failed to join one or more indispensable parties.

Forty-Third Affirmative Defense

Plaintiff's claims against Meijer are barred, in whole or in part, by the applicable statutes of limitations and repose.

Forty-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because they violate the *Ex Post Facto* clauses of Article I of the United States Constitution and Article II, Sec. 28 of the Ohio Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Forty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the free public services doctrine.

Forty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the economic loss and/or municipal cost recovery doctrine.

Forty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution as well as Article I, Section 16 of the Ohio Constitution, because substantive due process forbids the retroactive imposition and unclear legal interpretations of the Ohio Uniform Controlled Substances Act and its federal counterpart(s),

including, without limitation, the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act (“FDCA”).

Forty-Eighth Affirmative Defense

Meijer’s rights under the Due Process Clause of the U.S. Constitution and Ohio State Constitution or statutes are violated by any financial or other arrangement that might distort a government attorney’s duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff’s use of a contingency fee contract with private counsel.

Forty-Ninth Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Amended Complaint.

Fiftieth Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court’s decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

Fifty-First Affirmative Defense

Plaintiff’s claims are preempted insofar as they conflict with Congress’s purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. See *Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

Fifty-Second Affirmative Defense

To the extent Plaintiff asserts claims that depend solely on violations of federal law, including any claims with respect to Meijer’s compliance with statutes or regulations administered and/or

enforced by the DEA, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

Fifty-Third Affirmative Defense

Plaintiff's claims are barred to the extent they are based on any allegations involving failure to provide adequate warnings or information, because all warnings or information that accompanied the products at issue were approved by the United States Food & Drug Administration for products approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

Fifty-Fourth Affirmative Defense

To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish Meijer's regulatory duties, such informal guidance cannot enlarge Meijer's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

Fifty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

Fifty-Sixth Affirmative Defense

Meijer is not liable for any statements in the Manufacturer Defendants' or any other third party's branded or unbranded materials.

Fifty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the State of Ohio specifically licensed Meijer to distribute the controlled substances referred to in the Amended Complaint to those with valid prescriptions within the relevant Counties in Ohio.

Fifty-Eighth Affirmative Defense

Plaintiff's commencement and prosecution of this action is arbitrary and capricious, and its claims are contrary to the Ohio Uniform Controlled Substances Act and rules and regulations promulgated pursuant to that Act and its federal counterpart.

Fifty-Ninth Affirmative Defense

Plaintiff's claims against Meijer are barred, in whole or in part, because it has suffered no damages because of the matters alleged in the Amended Complaint.

Sixtieth Affirmative Defense

Plaintiff is not entitled to damages or an abatement remedy for costs it allegedly incurred or to be incurred in providing public services absent an express statutory provision establishing such a remedy.

Sixty-First Affirmative Defense

Any injuries and/or damages sustained by Plaintiff were caused, in whole or in part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff is barred or, alternatively, should be diminished according to its own fault.

Sixty-Second Affirmative Defense

Any verdict or judgment that might be recovered by Plaintiff may be barred or limited by the principles of informed consent and assumption of the risk, whether primary, express, or implied.

Sixty-Third Affirmative Defense

Meijer is entitled to a proportionate reduction, based on the negligence or other conduct of any settling tortfeasor, responsible third party, or Plaintiff, of any damages found against Meijer.

Sixty-Fourth Affirmative Defense

To the extent that Plaintiff seeks equitable relief against Meijer, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

Sixty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Meijer did not proximately cause the damages complained of, and because the acts of other persons (including individuals engaged in the illegal distribution or use of opioids without a proper prescription) intervened between Meijer's acts and Plaintiff's harms.

Sixty-Sixth Affirmative Defense

The injuries and damages claimed by Plaintiff resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Meijer was not the proximate and/or competent producing cause of such alleged injuries and damages.

Sixty-Seventh Affirmative Defense

Plaintiff's claims for unjust enrichment are barred because Plaintiff did not pay Meijer any of the amounts sought.

Sixty-Eighth Affirmative Defense

Plaintiff's public nuisance claim is barred to the extent Plaintiff lacks the statutory authority to bring a public nuisance claim under Ohio law and/or its own applicable codes or regulations.

Sixty-Ninth Affirmative Defense

Plaintiff's claim of public nuisance is barred or limited because no action of Meijer involved interference with real property; illegal conduct perpetrated by third parties involving the use of an

otherwise legal product does not involve a public right against Meijer sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of Meijer is too remote from the alleged injury as a matter of law and due process.

Seventieth Affirmative Defense

To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct for causes of action not already dismissed by the Court, Plaintiff has failed to plead fraud with sufficient particularity as required by the applicable rules of procedure and Meijer provided notice of all material facts.

Seventy-First Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Meijer did not engage in misleading, unfair, actionable misrepresentation, or deceptive conduct. Plaintiff fails to plead any actionable misrepresentation or omission made by or attributable to Meijer.

Seventy-Second Affirmative Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest because of the conduct of Meijer as alleged in the Amended Complaint.

Seventy-Third Affirmative Defense

Plaintiff may have failed or refused to exercise reasonable care and diligence to avoid loss and minimize damages and, therefore, may not recover for losses that could have been prevented by reasonable efforts on its part, or by expenditures which might reasonably have been made. Recovery, if any, should therefore be reduced by Plaintiff's failure to mitigate damages, if any.

Seventy-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because the claims are speculative, uncertain, hypothetical, and remote; and because of the impossibility of ascertaining and allocating the alleged damages.

Seventy-Fifth Affirmative Defense

Plaintiff's claims are barred to the extent they relate to Meijer's alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Ohio.

Seventy-Sixth Affirmative Defense

Plaintiff's claims are barred to the extent they rely, explicitly or implicitly, on a theory of market-share liability.

Seventy-Seventh Affirmative Defense

Plaintiff's claims for injunctive relief are barred because they are punitive in nature.

Seventy-Eighth Affirmative Defense

Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable Ohio statutory and common law regarding setoffs.

Seventy-Ninth Affirmative Defense

The DEA and the CSA regulations do not impose the system requirements claimed by Plaintiff. At all times, Meijer's systems satisfied all legal requirements.

Eightieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of acquiescence, settlement, or release.

Eighty-First Affirmative Defense

Plaintiff's claims are barred because Plaintiff seeks to impose liability on Meijer for fulfilling obligations imposed on Meijer by law.

Eighty-Second Affirmative Defense

Meijer pharmacists at all times followed dispensing practices that they were trained to follow, including pharmacy school, licensing board (Ohio Board of Pharmacy or "OHBOP") and continuing education, and they reasonably relied upon such sources.

Eighty-Third Affirmative Defense

Meijer and its pharmacists reasonably relied upon the OHBOP inspections which concluded that Meijer pharmacies' dispensing practices complied with applicable law including OHBOP requirements and regulations.

Eighty-Fourth Affirmative Defense

Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable portions of the Ohio Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it:

- a. lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any;
- b. is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties;

- c. unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff;
- d. permits the imposition of punitive damages where the burden of proof is less than clear and convincing evidence;
- e. permits the imposition of punitive damages without bifurcating the trial and trying all punitive damages issues separately, only if and after a finding on the merits of the liability of Meijer;
- f. permits the imposition of punitive damages without any predetermined limit on any such award;
- g. permits an imposition of punitive damages that allows for multiple punishments for the same alleged act(s) or omission(s);
- h. unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any;
- i. unconstitutionally may permit jury consideration of net worth or other financial information relating to Meijer;
- j. lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties;
- k. lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties;
- l. would unconstitutionally impose a penalty, criminal in nature, without affording Meijer the same procedural protections that are accorded to criminal defendants under the

constitutions of the United States, this State, and any other state whose laws may apply; and/or

- m. otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

Eighty-Fifth Affirmative Defense

Plaintiff fails to assert claims and allege facts specific to Meijer sufficient to imply its participation in a civil conspiracy.

Eighty-Sixth Affirmative Defense

To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 2 Stat. 1040, 21 U.S.C. §301.

Eighty-Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, for failure to exhaust administrative remedies or to satisfy other procedural prerequisites.

Eighty-Eighth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by unforeseeable and uncontrollable forces over which Meijer had no control and for which Meijer is not responsible, including without limitation pre-existing or unrelated medical conditions.

Eighty-Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the deference that common law accords discretionary actions by the FDA under the FDCA and discretionary actions by the DEA under the Controlled Substances Act.

Ninetieth Affirmative Defense

Plaintiff's claims are barred in whole or in part because Plaintiff suffered no injuries or damages as a result of any action by Meijer.

Ninety-First Affirmative Defense

Plaintiff has failed to join all necessary parties, including without limitation health care providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription or non-prescription opioid products.

Ninety-Second Affirmative Defense

Any damages in connection with any verdict or judgment that might be recovered by Plaintiff are capped pursuant to Ohio Revised Code §§ 2315.18 and 2315.21.

Ninety-Third Affirmative Defense

Plaintiff's common law and statutory public nuisance claims are barred or limited to the extent that they have been abrogated or otherwise curtailed by the Ohio Products Liability Act, Ohio Rev. Code § 2307.71, *et seq.*

Ninety-Fourth Affirmative Defense

Meijer is not liable for damages to the extent the methods, standards, or techniques of designing, manufacturing, labeling, and distributing the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA,

and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, and distributed.

Ninety-Fifth Affirmative Defense

Plaintiff's public nuisance claim is precluded by Ohio Rev. Code § 4729.25 and the Ohio Legislature's comprehensive regulation of drugs of abuse.

Ninety-Sixth Affirmative Defense

Meijer and its pharmacists reasonably relied upon the DEA which set annual national quotas for controlled substances based upon the country's legitimate medical needs and is responsible for the enforcement of the CSA.

Ninety-Seventh Affirmative Defense

Meijer cannot control and is not responsible for what patients do with prescription drugs after they are dispensed by pharmacists. Patients have a duty to use the drugs properly and store them safely.

Ninety-Eighth Affirmative Defense

Meijer pharmacists cannot interfere with and cannot be held responsible for the legitimate medical judgment of licensed prescribers.

Ninety-Ninth Affirmative Defense

Plaintiff's damages, if any, were caused by the active, direct, and proximate negligence or intentional conduct of entities or persons other than Meijer, and in the event that Meijer is found to be liable to Plaintiff, Meijer will be entitled to indemnification, contribution, and/or apportionment.

One Hundredth Affirmative Defense

Meijer hereby gives notice that it reserves the right to rely upon any other applicable defenses set forth in any Answer of any other Defendant in this action, reserves the right to rely upon any other

defenses that may become apparent during fact or expert discovery in this matter, and reserves their right to amend its Answer and to assert any such defenses.

Jury Demand

Meijer hereby requests a jury trial as to all issues or claims triable in this action.

WHEREFORE, Meijer requests that the Court enter judgment in favor of Meijer and against Plaintiff on all claims; award Meijer its costs and attorney fees; and grant Meijer such other and further relief as the Court deems proper.

Dated: September 21, 2021

Respectfully submitted,

/s/ Joseph M. Vanek

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and Meijer Stores Limited Partnership*

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served via the Court's CM/ECF system to all counsel of record.

/s/ Joseph M. Vanek